



ECRIN-ERIC Management Office

ECRIN-ON-BOARD

ECRIN (www.ecrin.org) launches in 2015 a campaign to provide early support to multinational clinical research projects preparing a Horizon 2020 (H2020) application for the SC1 2016 call. This "ECRIN-on-board" initiative requires principal investigators to send a draft synopsis of the proposed clinical study by early October 2015.

Based on this synopsis, ECRIN will be able to provide free support to the development of the project through:

- 1. Independent methodological consulting during protocol development, and independent review of the full protocol before H2020 application
- 2. Consulting on logistical and operational aspects of the clinical trial with focus on the international nature: regulatory and ethical aspects, insurance, contracting, monitoring strategy, costs, risk and mitigation, trial oversight boards, site identification and selection
- 3. Advice on clinical aspects of H2020 application: work package architecture, impact, management, governance and consortium, (however ECRIN will not draft the application)

This 2015 pilot initiative will be restricted to ECRIN-ERIC Member or Observer Countries.

Principal investigators are welcome to send a study synopsis (see attached template) summarising the medical need and planned study design, before October 5th 2015 to the ECRIN European Correspondents. These documents will be dealt with under strict confidentiality.

By October 15th, after endorsement of the synopsis by ECRIN, a methodologist from the ECRIN Scientific Board (SB) will be assigned to each study. The methodologist will assess the synopsis and will provide recommendations before the end of November.

Investigators will then be invited (optional) to submit the full protocol before January 15th, 2016 for independent review of the full protocol by the ECRIN SB. Comments will be circulated during the first week of March 2016. The H2020 application deadline is mid April 2016. If the full protocol is not reviewed by the ECRIN Scientific Board before the H2020 application, methodological advice will be given by the Scientific Board after the H2020 funding decision is made.

In parallel, consulting on operational and logistical aspects, as well as advice on H2020 application will be given for free by the European Correspondents and the ECRIN core team.